IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 2 CASES ATTACHED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DR. SHELBY THAMES

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames ("Dr. Thames"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Scientists from around the world, including Ethicon's own, have demonstrated time and time again that polypropylene, including the PROLENE polypropylene material used by Ethicon to manufacture its stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") devices, undergoes surface degradation after it is implanted in the body.[1,2,3,4,5,6,7,8,9,10,11,12,13] This

[1] Exhibit M – Liebert, et al., "Subcutaneous Implants of Polypropylene Filaments." *Journal of Biomedical Materials Research*, (1976) 10(6):939–951
[2] Exhibit N – Jongebloed et al., "Mechanical and biochemical effects of man-made fibers and metals in the human eye, a SEM-study, *Documenta Ophthalmologica* (1986) 61, 303-3012
[3] Exhibit O – Mary, et al., "Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery" *ASAIO Journal*, (1998) 44(3):199–206
[4] Exhibit P – Clavé, et al., "Polypropylene as a Reinforcement in Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants." *Int. Urogynecology J.*, (2010) 21(3):261–270
[5] Exhibit Q – Costello, et al., "Characterization of Heavyweight and Lightweight Poly." *J. Biomed. Mater. Res. B Appl. Biomater.*, (2007) 83B(1):44–49;

fact was further confirmed by Ethicon's former scientist, Dr. Thomas Barbolt, who admitted under oath as Ethicon's 30(b)(6)[14] corporate representative that PROLENE does indeed undergo *in vivo* surface degradation and that Ethicon was aware of this phenomenon several years before it started selling Prolene-based SUI and POP kit devices in the United States and well in advance of disseminating misleading information in Ethicon's product labeling which erroneously claimed that these products were not subject to *in vivo* degradation.

Dr. Barbolt's admissions are damaging to Ethicon on several fronts as his testimony demonstrates that Ethicon's Prolene-based products were defectively designed, that Ethicon was aware of this design defect before it placed these implants on the market and, further, that Ethicon committed fraud when it misrepresented in its product labeling that these devices did not degrade. Recognizing this, Ethicon retained a number of material scientists, like Dr. Thames, who offer contradictory opinions and testimony concerning Prolene's propensity to degrade. This is a clear attempt by Ethicon to undo the position it has already taken under oath by virtue

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[6] Exhibit R - Costello et al., "Materials Characterization of Explanted Polypropylene Hernia Meshes," *J. Biomed. Mater. Res. B Appl. Biomater.*, (2007) 83B(1):44–49.
[7] Exhibit S – Wood, et al. "Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient." *J. Mater. Sci. Mater. Med.*, (2013) 24(4):1113–1122
[8] Exhibit T – Crack Depth In Explanted Prolene Sutures (June 15, 1982), ETH.MESH.12831405
[9] Exhibit U – Prolene (Polypropylene) Microcracks memo (March 23, 1983), ETH.MESH.15955438
[10] Exhibit V – Human Retrieval Specimens From Dr. Roger Gregory, Norfolk Surgical Group memo (March 29, 1983), ETH.MESH.15955440 (Ethicon's scientists used the same histological methods employed by Dr. Iakovlev to identify surface cracks observed on explanted Prolene sutures)
[11] Exhibit W – Examination of Prolene (Polypropylene) Sutures from Human Cardiovascular Explants memo (May 2, 1984), ETH.MESH.15955462 (Ethicon's scientists using the same histological methods as Dr. Iakovlev found that the explanted PROLENE suture had degraded in vivo. The histological stain penetrated the degraded PROLENE fiber. Blue dye particles were observed within the cracked layer confirming that cracked layer was PROLENE polypropyrlene and not a protein coating on the PROLENE strands)
[12] Exhibit X – IR Microscopy of Explanted PROLENE Received from Prof. R. Guidoin (Sept. 30, 1987), ETH.MESH.12831391-1404
[13] Exhibit Y – Seven Year Dog Study (Prolene 7-Year Dog Study) (Oct. 15, 1992), at ETH.MESH.09888220
[14] Fed.R.Civ.P. 30(b)(6)

of Dr. Barbolt's corporate witness designation and testimony. However, pursuant to Rule 30(b)(6) Ethicon is bound by Dr. Barbolt's admissions no matter how damaging they are and, as a result, Ethicon should be precluded from offering any evidence that contradicts the admissions of Dr. Barbolt, including any testimony by Dr. Thames that Prolene does not degrade.

Furthermore, Dr. Thames' opinions concerning Prolene degradation should be excluded at trial as they are unreliable and unsupported by decades of scientific evidence(including Ethicon's own internal studies), they are self-contradictory and they even go as far as to misstate evidence to fit his opinions. Dr. Thames is eager to defend Ethicon's Prolene material and explain why he *believes* that Prolene does not degrade, but many of the opinions in his report cannot be allowed at trial. As an expert witness, Dr. Thames has the burden to provide scientifically sound support for every opinion in his report—and he simply has not done that with respect to degradation, molecular weight and toughness.

In addition, Dr. Thames used a protocol for cleaning explanted meshes that is fundamentally flawed. He did not perform proper controls to test if his cleaning process, itself, was destroying evidence of oxidation on Plaintiffs' meshes. This fact is established by his own testimony and it renders all of his testing and analysis—and any opinions generated therefrom—completely unreliable. As such, any mention of his testing and analysis should be excluded from trial.

Moreover, Dr. Thames' Prolene-specific opinions and cleaning methodology are unscientific and unreliable as, by his own admission, Dr. Thames would require 1,000% certainty before he would concede that Ethicon's Prolene material undergoes *in vivo* surface degradation. This is an impossible—and completely unscientific—standard.[15] This kind of zealousness is what allows Dr. Thames to offer opinions that are wholly unsupported by

[15] Exhibit E Thames Dep. at 45:747:10.

evidence and which contradict the testimony of Ethicon's 30(b)(6) witness. For these reasons and as set forth in greater detail below, Dr. Thames should be precluded from offering his Prolene-specific opinions at trial.

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed.R.Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Thames to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Thames is qualified and the testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014)

reconsideration denied, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, Dr. Thames can only offer testimony that is "fit" for the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id*.

ARGUMENT

When Dr. Thames testified before this Court in the *Huskey v. Ethicon* matter, his *beliefs* about the unique characteristics of Prolene were not challenged by the Plaintiffs before trial and his testimony on direct examination focused on whether or not several peer-reviewed publications addressed Prolene's oxidation specifically.[16] His general causation Wave 2 report, however, puts forth many opinions that should not be heard by any jury. Those opinions are not only unsupported, but they contradict themselves, the peer-reviewed literature, decades of Ethicon's own internal studies and the testimony of Ethicon's 30(b)(6) corporate designee confirming Prolene's tendency to degrade. As such, Dr. Thames must be limited to what he can testify about at trial.

I. The defendants have already admitted under oath through their 30(b)(6) corporate witness, Dr. Thomas Barbolt, that the Prolene used in their SUI and POP mesh products undergoes *in vivo* degradation.

In accordance with the requirements of Rule 30(b)(6), Ethicon designated Dr. Thomas Barbolt as its 30(b)(6) corporate designee on the subject of Prolene's ability to degrade *in vivo*. Dr. Barbolt testified unequivocally throughout his deposition that Prolene undergoes *in vivo* surface degradation and that Ethicon knew this several years prior to disseminating misinformation to physicians in its labeling which erroneously claims that Prolene does not degrade:

[16] Exhibit B - *Huskey v. Ethicon* trial, Day 7 at 74-91

Q.So you would agree as a spokesperson - - as a 30(b)(6) person for Ethicon that the surface of polymer fibers, including the polypropylene fibers in TVT, can crack?

A.Yes.[17]

…

Q.Despite the antioxidants being added to the Prolene sutures, in two of the Prolene sutures in the study, the surface layer was cracked, correct?

A.Two revealed cracking, yes.

Q.And you aren't suggesting to the ladies and gentlemen of the jury that those cracks were anything other than the Prolene polypropylene, are you?

A.No, I am not suggesting that, and that's not reflected in this report.

Q.You would agree that the surface that's cracked here is the polypropylene surface layer, correct?

A.In reading the report, it says that – that's what I would conclude.[18]

…

Q.And that's Ethicon's position as you -- as the spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct?

A.Yes.

Q.And this was known well in advance of this statement that the material is not absorbed, nor is it subject to degradation, correct?

A.Yes. This is from 1992.[19]

Thus, Ethicon is bound by the admissions of its 30(b)(6) corporate designee that their Prolene-based SUI and POP mesh products degradation. Despite this, Dr. Thames' opinions contradict the testimony provided by Dr. Barbolt. Ethicon should be precluded from undoing the testimony of its 30(b)(6) corporate designee simply because his answers contradict what has been promoted publically about its mesh products.

[17] Exhibit C - Excerpt from Barbolt Dep., 1/8/2014, at 385:14-20
[18] Exhibit C - Excerpt from Barbolt Dep., 1/8/2014, at 396:2-23
[19] Exhibit C - Excerpt from Barbolt Dep., 1/8/2014, at 409:2-13 (emphasis added). See also *Id* at 360:20-25

Under similar circumstances, federal court judges have precluded litigants from doing what Ethicon is attempting to do here. For example, in *Rainey v. American Forest & Paper Ass'n. Inc.*, 26 F. Supp.2d 82, 94 (D.D.C. 1998), the defendants had designated 30(b)(6) witnesses whose binding testimony failed to create a material issue in dispute. The plaintiff moved for summary judgment and in response, the defendants provided an affidavit of a former employee who provided new testimony that contradicted the testimony provided by the designated 30(b)(6) corporate witness. There, the District Court precluded the defendants from offering new evidence or testimony inconsistent with the testimony of the corporate 30(b)(6) designee, holding that the:

> Plaintiff's theory is consistent with both the letter and spirit of Rule 30(b)(6). First, the Rule states plainly that persons designated as corporate representatives "shall testify as to matters known or reasonably available to the organization." Fed.R.Civ.P. 30(b)(6). This makes clear that a designee is not simply testifying about matters within his or her own personal knowledge, but rather is "speaking for the corporation" about matters to which the corporation has reasonable access. *United States v. Taylor,* 166 F.R.D. 356, 361 (M.D.N.C.1996), *aff'd United States v. Taylor,* 166 F.R.D. 367 (M.D.N.C.1996) (quoting 8A Charles Alan Wright *et al.,* Federal Practice and Procedure, § 2103, at 36–37 (2d ed.1994)). By commissioning the designee as the voice of the corporation, the Rule obligates a corporate party "to prepare its designee to be able to give binding answers" in its behalf. *Ierardi v. Lorillard, Inc.,* 1991 WL 158911, at *3 (E.D.Pa. Aug.13, 1991); *Taylor,* 166 F.R.D. at 361 (designee "presents the corporation's 'position' on the topic") (internal citation omitted). *Unless it can prove that the information was not known or was inaccessible, a corporation cannot later proffer new or different allegations that could have been made at the time of the 30(b)(6) deposition.* See *Ierardi,* 1991 WL 158911, at *3; *Taylor,* 166 F.R.D. at 362.

Id at 94 (emphasis added). This is exactly what the Defendants are attempting to do with Dr. Thames. His opinions concerning Prolene's propensity to degrade wholly contradict the testimony of Ethicon's corporate representative, Dr. Thomas Barbolt. For this reason alone, Dr.

Thames should be excluded from offering opinions or testimony at trial that Prolene does not undergo *in vivo* degradation.

II. Dr. Thames' Prolene-specific opinions are at conflict with the available evidence and they are completely unsupported.

Dr. Thames' expert report is at conflict with itself. The Prolene-specific opinions described in his report not only disagree with the available scientific literature and Ethicon's 30(b)(6) corporate designee, but they also contradict decades of internal reports and conclusions on how Prolene's oxidation causes degradation, environmental stress cracking, losses in molecular weight, and losses in its mechanical properties after implantation. Dr. Thames offers no peer-reviewed support for his Prolene opinions and instead, he manipulates the findings from one of the internal studies that he discredits (the seven year dog study) to bolster his *belief* "that Ethicon's Prolene material used in its mesh products does not undergo meaningful or harmful degradation *in vivo.*"[20] Further, and without providing any evidence that Prolene is inert after implantation, his report states that "[a]t the time of this writing, I have seen no scientifically sound evidence to prove Ethicon's Prolene mesh oxidizes *in vivo.*"[21]

Dr. Thames has the burden to show that his Prolene-specific opinions are reliable—it is not enough for him to disagree with all of the available science and simply state that he needs to see more evidence to be convinced that Prolene undergoes changes *in vivo*. Indeed, as he told Plaintiffs' counsel, he needs to be 1,000% certain that oxidation is taking place,[22] but this is not the standard by which testimony is reliable under *Daubert* and its progeny. Dr. Thames must "come forward with evidence from which the court can determine that the proffered testimony is

[20] Exhibit D - Dr. Thames Wave 2 General report at 13
[21] *Id.*
[22] Exhibit E - Thames General Deposition at 45:747:10.

properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998). The defense may have no burden of proof on the claims at issue, but Dr. Thames still needs scientific support to proffer his opinions and he has provided nothing reliable to support his opinion that Prolene does not degrade or that it is inert inside the body.

Dr. Thames is attempting to place the burden on the Plaintiffs to disprove his Prolene-specific opinions and he cannot do that. Under *Daubert* he has to show the Court that this plastic does not change or degrade *in vivo* if he is going to testify about it at trial. Indeed, his report admits that Prolene was found to change after implantation—he just prefers to use the phrase "aging process" instead of "degradation" and believes that the mechanical changes (losses in strength, gains in elasticity and losses modulus) should be viewed positively and that they are not due to losses in molecular weight and degradation. [23] Yet this opinion is in direct opposition to his report's admission that "it is well known that molecular weight reductions adversely affect physical properties."[24] Even further, the one Prolene-specific study that he uses to support his opinions specifically concluded that "[d]egradation in PROLENE is still increasing [over time *in vivo*] and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."[25] Moreover, and as explained below, Dr. Thames' bases all of his Prolene opinions on evidence that is manipulated to fit his defense of the material.

III. Dr. Thames manipulates Prolene's molecular weight degradation evidence to fit his opinions.

Dr. Thames' report states that the "seven year data confirmed no *significant* difference in molecular weights for the 4/0 Prolene control suture and the seven year explants"—which is

[23] Exhibit D - Dr. Thames Wave 2 General report at 3 and 6
[24] *Id*. at 8
[25] Exhibit F - ETH.MESH.05453719

almost verbatim what the results of Mr. Burkley's dog study stated.[26] Importantly, however, the results of that dog study do not state that there were *no changes* in molecular weight—they state that there were changes, but that Mr. Burkley did not consider them to be *significant*. Mr. Burkley confirmed this fact at his deposition and so did Ethicon's 30(b)(6) corporate designee, Dr. Thomas Barbolt.[27]

Plaintiffs note that Dr. Thames' Wave 2 report has been altered from his Wave 1 report to remove several instances where it previously and incorrectly stated that the Burkley dog study found *no changes* in molecular weight. However, Dr. Thames' Wave 2 report still states:

> "both Burkley and Jordi independently determined unequivocally that Prolene does not degrade (no MW loss) *in vivo*. Therefore, no degradation of Prolene occurs in-vivo, as molecular weight loss is a form of degradation, i.e. no degradation, no molecular weight loss." [28]

This is not a true statement. The dog study itself concluded oxidation was taking place and the data showed that Prolene gained elasticity and lost strength and modulus *in vivo*, and the testimony from Dan Burkley and the testimony from Dr. Thomas Barbolt, Ethicon's 30(b)(6) corporate designee, say the same thing.[29]

Indeed, immediately before stating that there were no molecular weight losses found, Dr. Thames' report states the truth of the matter:

> "Dr. Jordi wrote "The Jordi GPC analysis of both control and explant samples tend to confirm "The 7 year Dog Study" performed at Ethicon referred to as Exhibit T-2182 in his (Burkley's) deposition of May 22, 2013, in that little to no macro Mw degradation was noted.""[30]

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[26] Exhibit D - Dr. Thames Wave 2 General report at 6 (emphasis added)
[27] Exhibit G - Deposition of Dan Burkley, May 22, 2013 at 154:22-155:1; See also Exhibit C - Excerpt from Barbolt Dep., 1/8/2014, at 409:2-13, 360:20-25, 396:2-233, 85:14-20.
[28] Exhibit D - Dr. Thames Wave 2 General report at 29
[29] Exhibit F - ETH.MESH.05453719; Exhibit G - Deposition of Dan Burkley, May 22, 2013 at 154:22-155:1; ; See also Exhibit C – Barbolt Dep., 1/8/2014, at 409:2-13, 360:20-25, 396:2-233, 85:14-20
[30] Exhibit D - Dr. Thames Wave 2 General report at 28

Little to no macro molecular weight degradation was noted by Dr. Jordi or internally by Dan Burkley—this is a true statement, but it does not mean changes were not seen on the smaller scale.

The peer reviewed literature reported on this phenomenon in 1998: only the surface of the material is being continually oxidized and degraded *in vivo*—meaning the bulk of the polypropylene (*the macro*) from explanted Prolene will be relatively unchanged.[31] Dr. Thames is mischaracterizing the available evidence when he states that there were *no changes* found to Prolene's molecular weight. He has nothing to support that statement—and it is a complete manipulation of the available evidence. It needs to be precluded at trial.

IV. Dr. Thames cannot determine Prolene's "toughness" from the tensile testing data collected from year 7 of the dog study.

Similarly, Dr. Thames has no basis to opine that the data from year 7 of the dog study "validates toughness improvement after initial implantation."[32] Dr. Thames provides no description or references showing how he determined toughness from the dog study, there is no statement about toughness made in the study itself, and there is no support for this opinion at Ethicon.[33] Indeed, Dr. Thomas Barbolt, the 30(b)(6) witness designated by Ethicon to testify about how Prolene behaves *in vivo*, explained that a surface reaction is taking place and that Prolene oxidizes and its properties degrade after implantation.[34]

Dr. Thames' report even describes several negative changes to Prolene that were recorded in year 7 of the dog study: "[t]he elongation of explanted sutures increased 111% over

[31] Exhibit H - Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206.
[32] Exhibit D - Dr. Thames Wave 2 General report at 7
[33] Exhibit D - Dr. Thames Wave 2 General report at 6-9.
[34] Exhibit C – Barbolt Dep., 1/8/2014, at 409:2-13, 360:20-25, 396:2-233, 85:14-20

the seven year period, tensile strength diminished by only 5%, and modulus decreased by 70%."[35] In other words, the testing showed that Prolene sutures lost all of their mechanical properties—the sutures were weaker (losses in tensile strength), more likely to stretch (gains in elasticity) and lost their ability to return to their original form (losses in modulus). Yet Dr. Thames' report does not address how those negative results can support his opinion that those sutures gained toughness and did not degrade. Indeed, his report admits that Prolene was found to change after implantation—he just prefers to call those changes part of Prolene's "aging process" instead of its "degradation."[36]

First of all, Dr. Thames references the effect that plasticization can have on the toughness of polymers, but there are no plasticizers in Ethicon's Prolene and Dr. Thames has not explained the chemistry of how the sutures somehow became plasticized or toughened *in vivo*.[37] Furthermore, **Figure 5** of his report illustrates how the "toughness" of a material can be determined by plotting the amount of stress placed on a material against the amount of strain measured and "[t]oughness is defined as the area under the stress-strain curve."[38] Dr. Thames' report, however, contains no stress-strain curve from the dog study nor could it possibly contain the underlying data needed to plot such a curve—because that data, which would have measured each suture's reaction to stress several times, was never collected.

Instead, Figure 6 only plots one point from year 7: the average weight placed when the sutures broke ("break strength") on the Y-axis against the average percent elongation when the sutures broke ("percent elongation") on the X-axis.[39] This is not a stress-strain curve—*this isn't even a curve*. Figure 6 only identifies one plot of two data points, with a line is drawn from it to

[35] Exhibit D - Dr. Thames Wave 2 General report at 6
[36] *Id.* at 2
[37] *Id.* at 7-8
[38] *Id.*
[39] *Id.* at 8

zero. A stress strain curve, like the ones shown in Dr. Thames' Figure 5 have multiple data points collected at different stress levels, not just one plot point that is connected to zero. This is simply not how a material's "toughness" is measured, which was the whole point of Dr. Thames' explanation of Figure 5.[40]

In addition, the tensile testing that Dr. Thames focuses on was only done on six Prolene sutures that were explanted from four dogs after 7 years of implantation.[41] There was, however, tensile testing performed in years 1 and 2, but that data is omitted from Dr. Thames' toughness opinions—and instead he only focuses on year 7. [42]

Moreover, Dr. Thames bases his toughness opinions, in part, on his manipulation and omission of the dog study's findings.

> Q. Let me ask this question, then. In the dog study, that was a study done by Burkley.
> A. Yes, sir.
> Q. B-U-R-K-L-E-Y. Did Dr. Burkley conclude that oxidative degradation took place?
> A. He indicated that there might be some oxidative degradation, and he was wrong. Because if there had been, you would not see a [stress strain] curve like this. It's impossible to have oxidative degradation and have that curve of physical properties and **no loss in molecular weight**.
> Q. Okay.
> A. They go together. It's like being married and having your first child. You know, carbonyl group formation, loss in molecular weight and physical properties, they all go together.[43]

[40] Plaintiffs' expert Dr. Guelcher agrees that toughness cannot be determined from Figure 6 in Dr. Thames' report: "I need to see the actual stress-strain curve. I need to know the stress at 1 percent elongation, 5 percent elongation, 10 percent, until it breaks. And from that stress-strain curve, you can do more analysis. But this is simply a plot of break strength versus elongation at break. And I – I can't make those kinds of inferences that you're trying to get me to agree to." Exhibit I, Dr. Guelcher Wave 1 deposition at 184:6-15

[41] Exhibit D - Dr. Thames Wave 2 General report at 28

[42] Exhibit F - ETH.MESH.05453719

[43] Exhibit – E - Thames Dep. at 135:21-136:12 (emphasis added)

This explanation needs unpacking. First of all, Dr. Thames is taking liberties with the available evidence when he states that there were *no changes* in molecular weight recorded in the dog study—and he should be precluded from saying that at trial. Secondly, because there actually was degradation seen in the dog study, Dr. Thames' toughness opinions cannot stand—and his above testimony bares that out, and so does his reports' admission that the sutures gained elasticity and lost strength and modulus *in vivo*.[44] And finally, his unsupported and unexplained "toughness" opinions cannot be used to negate all of the internal studies that concluded Prolene oxidizes, degrades, and loses molecular weight inside the body—he has the burden of providing testimony that is reliable—and he has not done that here.

Equally important is the fact that Dr. Thames does not provide any statistical significance for his toughness opinions—and that information needs to be in his report for his opinions to carry any weight to all of the Plaintiffs implanted with Prolene products. He is the one opining that Prolene is unlike every of polypropylene blend in existence and does not oxidize—and he has the burden to show that the opinions he garnered from the testing done on 6 sutures can apply to all of Ethicon's Prolene-containing products.

The data Dr. Thames focuses on from this internal study tells us this: that in one experiment—and after 7 years of implantation in dogs—6 Prolene sutures changed *in vivo* and lost their original mechanical properties. Dr. Thames is trying to polish that negative data into an opinion that the toughness of the sutures were somehow improved, but he can't do that and he certainly didn't explain any of that in his report.

His toughness opinion not only ignores the tensile data from years 1 and 2, it lacks statistical significance, the proper data was not recorded in the dog study itself, he ignores the fact that all of the mechanical properties of those sutures degraded (strength, elongation, and

[44] Id; Exhibit D - Dr. Thames Wave 2 General report at 6

modulus), and he bases this opinion on his repeated and mistaken assertion that there were *no changes* in molecular weight to Prolene recorded. There is absolutely no basis for him to testify about an increased toughness—it is not a scientifically reliable opinion and it must be precluded from trial.

V. Dr. Thames' opinions on the presence of extrusion lines and translucent flakes on explanted mesh are unsupported and must be excluded.

Dr. Thames' opinions regarding the presence of extrusion lines and translucent flakes on explanted mesh have no basis in the scientific method and no backing in the peer-reviewed literature—they are simply inadmissible *ipse dixit* opinions and need to be precluded. First, he opines that he sees translucent flakes on explanted blue fibers of Prolene, and because they are translucent, he believes that they are protein and not degraded polypropylene. But Dr. Thames cannot cite to any literature or support for that opinion:

> Q. And then you have identified one portion from a clear suture that has a translucent flake; is that right?
>
> A. Yes, sir, correct.
>
> Q. So that was the first part of what I'm asking you. The second part of what I'm asking you is, do you have anything to back up the fact that -- what you've just found?
>
> A: I think I have described it as efficiently as I am capable of describing it.
>
> Q. But you don't have any research to back it up?
>
> A: What is your definition of "research"?
>
> Q. Something in a peer review.
>
> A. Peer review?
>
> Q. Yes.
>
> A. Sir, we do research to put stuff in the peer review. Not everything that's researched is in the peer review.

> Q. I understand that. But you don't have anything in a peer review to support what you're stating in this report for Ms. Stubblefield; is that right?
>
> A: Peer review? This will go in the literature to be peer reviewed. But, **no, this is my finding,** and I think it's very clear and that most anyone will be able to understand it. Because not only do we find this here, we find it in 19 other cases just like this.[45]

Dr. Thames also seeks to proffer completely unsupported opinions about the presence of extrusion lines on explanted mesh:

> Q: With respect to your SEM opinions, do you have anything in a peer review literature that would support the opinion that the extrusion lines would degrade along with the outer surface of the Prolene fiber?
>
> A If there was oxidation of Prolene, it is my opinion that extrusion lines would be interfered with. They are not here. **I have not seen that written in another document, is my belief.** And you can see the extrusion lines being maintained all the way from an SEM -- well, about one, but certainly three. And you can see the transverse cracking and extrusion lines are still there.[46]
>
> …
>
> Q: Your report at the top of page 12 states, "If the surface of the Prolene fibers had degraded as postulated by plaintiff's expert, the extrusion lines would degrade during this process and would no longer be visible. That is not the case we observed." Do you see that?
>
> A. Yeah.
>
> Q. Can you tell me any support for that statement that you might have?
>
> A. **That's my belief**.[47]

Regardless of what Dr. Thames *believes* to be true, if he cannot substantiate or support those beliefs in any meaningful way, they should not be heard by any jury. *Daubert*, 509 U.S. at 590 (in the context of Rule 702, knowledge "connotes more than subjective belief or

[45] Exhibit J - Dr. Thames deposition for the Stubblefield case at 47:3-48:18 (objections omitted) (emphasis added)
[46] Exhibit K - Dr. Thames deposition for the Daino case at 29:13-30:1
[47] Exhibit J - Dr. Thames deposition for the Stubblefield case at 84:15-25; *See also* Exhibit L - Dr. Thames deposition for the Shelton case at 27:5-28:4, Rough draft.

unsupported speculation."). His testimony must be relevant and reliable, and he has the burden to prove that it is admissible. *Maryland Cas. Co*, 137 F.3d at 783. He has not shown that either of these opinions is reliable or scientifically sound. As such, any testimony about the presence of clear or colored flakes on explanted mesh, or about the presence of extrusion lines on explanted mesh, should be excluded.

VI. Dr. Thames' opinions on the presence of extrusion lines and translucent flakes on explanted mesh are the tainted result of a flawed cleaning protocol and it renders all of his testing-related opinions completely unreliable.

Dr. Thames seeks to opine that none of the mesh explants he examined showed signs of oxidation, but his testing—and any related testimony—should be excluded because Dr. Thames' cleaning protocol would have destroyed any evidence of oxidation that existed on those meshes. Dr. Thames' protocol calls for up to 23 steps to be performed on the meshes he examined.[48] Those steps include the use of Proteinase-K, sonication and shaking, water, heat and bleach—all of which could have destroyed evidence of surface oxidation. But Dr. Thames did not determine what effect, if any, the various steps of his cleaning protocol had on oxidized Prolene. He *assumed* there would be none even though the peer reviewed literature from 1998 described that stresses like shaking and sonication would remove the outer degraded layer from explanted Prolene:

> "Because this cracking is confined to the outer skin, which is clearly distinguishable from the inner core structure, it is not surprising to observe that, during abrasive stresses, such as cleaning, there was a tendency for the cracked rings at the surface to flake off and separate from the underlying core material."[49]

[48] Exhibit D Thames Wave 2 report at 99-102

[49] Exhibit H - Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206

Dr. Thames has admitted the importance of running a proper control in his line of work; as he told plaintiffs' counsel: "[n]o control, your data is of no significance."[50] That is exactly the situation we have here—the data he collected and the opinions he garnered about extrusion lines and translucent flakes from that testing are of no significance. Dr. Thames has not tested and, therefore, he cannot describe what the various steps of his cleaning protocol would do to any oxidation that was on the meshes that he examined. And he even explained at his deposition that one of the steps, the use of Proteinase-K, was intended to destroy the very evidence of oxidation that he was supposedly trying to find:

> Q. Your cleaning procedure actually involves a few more things than just water, heat and bleach, --
>
> A. Yes.
>
> Q. -- in all fairness, doesn't it?
>
> A. Yes, sir. We use protein to -- which in the event there's still clean protein, it will help remove some of it. It's an enzyme called Proteinase K, P-R-O-T-E-I-N-A-S-E-K, I believe.
>
> Q. So you used some Proteinase K?
>
> A. Yes, sir. It's an enzyme.
>
> Q. And what does that do?
>
> A. **Well, it helps open the proteins and the flesh more so that if there's any carbonyl groups that are there that haven't been removed, they're taken away**. It's just another cleaning process basically, a little bit more rigorous. But it's an enzyme. It's a mild enzyme, but it works a different way.[51]

Yet Dr. Thames also explained that the presence of carbonyl groups on explanted mesh *is what you would find* if you had evidence of oxidation.[52] But he chose to clean Plaintiffs' meshes with an enzyme that would destroy that very evidence. Even worse, Dr. Thames did not run a

[50] Exhibit E - Dr. Thames General Deposition at 52:24-25
[51] Exhibit E - Dr. Thames General Deposition at 61:16-62:9
[52] Id. at 46:12-48:19

control of purposefully oxidized polypropylene through any of the steps of his cleaning protocol to test *if* it would destroy evidence of oxidation on Plaintiffs' meshes:

> Q. So with respect to the FTIR that we're looking at, I've already given you two ranges, one where a hydroxyl group would be and one where a carbonyl is. Did you run a control where you had a piece of Prolene that had a hydroxyl group on it or had a carbonyl on it and run it through your protocol to make sure that your protocol did not destroy that oxidized Prolene?
>
> A. I ran an exemplar of Prolene and found that nothing changed on its surface during this period of time, which means that, therefore, if there was something on the explant, it would still be there when I finally got through step five, that I would not have removed it, and it would still be there.[53]
>
> …
>
> Q. What I mean to say is that for any one of the steps, we're talking about the -- let's just stick with the Proteinase K. Did you put -- did you purposefully oxidize Prolene and then put it through that step of the cleaning process?
>
> A. No, sir.
>
> Q. And did you do that with any of the steps of the cleaning process?
>
> A. No, sir.[54]

What Dr. Thames did by employing this cleaning protocol was to run a rigged game. According to Dr. Thames, Proteinase K takes away carbonyls, but carbonyls are also what would be present on the mesh if it was oxidized.[55] Also, he chose to employ sonication and shaking even though the peer reviewed literature explained that that is how you would remove the outer-degraded layer from explanted Prolene. Hence, his analysis of all of the meshes he examined would never have been able to find evidence of mesh oxidation—because his cleaning protocol was destroying it.

[53] Exhibit J - Dr. Thames Deposition in the Stubblefield case at 64:7-23
[54] Exhibit K - Dr. Thames Deposition in the Daino case at 21:3-16
[55] Exhibit E - Dr. Thames General Deposition at 46:12-48:19 and 61:16-62:9

Dr. Thames also has no idea what the other steps of his cleaning protocol would do to any oxidized Prolene—because he did not run a control of it to test any of them. This renders any testimony about the plaintiff-specific examinations he performed completely unreliable and, as Dr. Thames himself would say, "of no significance."[56] As such, the case specific testing is unreliable and he should not be allowed to testify about any opinions generated from the results of it at trial.

CONCLUSION

For the foregoing reasons, Dr. Thames should be limited in what he can testify about in these Wave 1 cases. No jury should ever hear any evidence that is unreliable—and the *ipse dixit* and unsupported statements by Dr. Thames complained about in this brief should be precluded. In addition, he has no basis to offer any case-specific opinions because his cleaning protocol likely destroyed whatever evidence of oxidation was originally on the meshes that he examined. Plaintiffs respectfully request their Motion be granted.

Dated: July 21, 2016

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[56] *Id*. at 47:3-10; 52:24-25

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace
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